Therabron Therapeutics

9430 Key West Avenue, Suite 150
Rockville, MD 20850

**VACANCY ANNOUNCEMENT**

**Director, Regulatory Affairs**

**Position summary:** Responsible for regulatory matter. The Director of Regulatory Affairs will work collaboratively with the company's clinical, manufacturing and quality functions to ensure robust and compelling interactions with governing regulatory agencies.

**Key responsibilities:** Oversee the development and implementation of regulatory affairs programs to assure conformity with all applicable federal and state statutes, guidelines and regulations governing drug development activities. The Director is responsible for developing regulatory strategies, preparing all submissions to regulatory authorities, assuring that regulatory documents are in compliance with all regulations and other requirements, and is primary point of contact with all regulatory authorities. The position involves the ability to integrate and apply knowledge of US (and ideally EU) regulations governing drug development to our client's quality, preclinical, and clinical programs.

**Duties and Responsibilities include the following (other duties may be assigned):**

- Develop regulatory strategies for programs in collaboration with Company Executives including review and analysis of guidances, policies, regulations and assessment of similar drugs to meet development milestones. Develop and implement strategies for the most efficient and timely submission and approval of regulatory filings.
- Participate in multidisciplinary project team to provide regulatory guidance and communicate regulatory goals.
- Provide regulatory advice for potential new projects and guidance on regulatory requirements to support product development.
- Collaborate with project teams on study design, statistical analysis plans, and integrated analysis plans.
- Collaborate with teams to perform critical analyses of data (clinical, preclinical and manufacturing) and independently develop interpretations and conclusions.
- Perform reviews of clinical protocols and study reports with respect to scientific rigor, clarity, completeness, and regulatory requirements.
- Lead multidisciplinary teams in the preparation of regulatory communications such as regulatory briefing packages.
- Develop working processes to ensure cross-department standardization and to foster more efficient forward thinking approaches.
- Continually monitor FDA guidelines in the context of new and ongoing development programs.
- Participate in liaison activities with regulatory authorities, including overseeing the preparation of pre-meeting briefing materials, the preparation for and facilitating sponsor interactions at regulatory meetings, and ensuring appropriate follow-up.
- Manage and execute regulatory activities, including IND filings and other regulatory submission and maintenance of US and ex-US regulatory filings.
- In conjunction with other stakeholders, identify, develop, draft and review SOPs dealing with regulatory affairs activities and responsibilities.

**Qualifications:**

- Bachelor's degree in life sciences or chemistry. An advanced life science degree (e.g. MS, PhD) is preferred.
- Minimum of 10 years' experience in pharmaceutical / biotechnology regulatory affairs
- Substantive experience in regulatory operations, especially submission publishing and strong knowledge of eCTD software and FDA electronic submission requirements.
- Solid working knowledge of FDA organization, policies and biologics regulatory requirements.
- Knowledge of regulations and guidelines regarding drug development, regulatory submissions and corresponding regulatory agency interactions.
- Strong strategic and analytical abilities, diplomacy, negotiation and excellent oral and written communications skills; highly organized.
- Proven ability to interact in a group environment, have strong interpersonal skills and the ability to establish and maintain effective relationships with all stakeholders
- Requirements include a thorough understanding of GLP, GCP, GMP, FDA and ICH guidelines, excellent written and oral communication skills, a detail-oriented work style and the ability to handle multiple tasks. Must be able to work under pressure and meet deadlines. Incumbent must have the ability to present facts and recommendations effectively in oral and written form.
- Experience with EMA regulations and policies
- Experience with biologics submissions
- Experience with dossier filings with Pulmonary & Allergy Division a strong plus.